



# By the Numbers

Since its inception in 2015, TPIRC & Food Allergy Institute have helped more than 8,000+ families achieve remission from food allergies. This includes children and young adults suffering from severe and complex allergic conditions. Our Tolerance Induction Program™ (TIP) aims to create a world where children everywhere can live free from the fear of food-induced anaphylaxis.

<1%

Reaction Rate

18 mos. - 25 yrs.

Age range of patients
enrolled in TIP

9+

Treats all major food allergies



8,000+

Patients Achieved Remission

130+

Average # of different allergens tested

56,228 +

Annual in-clinic food introductions and challenges

4,000+

Annual lab draws performed

250+

Employees covering a diverse range of expertise spanning five medical specialties, AI, data science, food manufacturing, diagnostic testing, clinical research, and more.



3 million+

Pharmaceutical grade gummies produced

1.8 million+

Annual at-home treatment doses

12

Physicians

17

**Physician Assistants** 

9

**Nurse Practitioners** 

16

Nurses

50

Food Challenge Exam Rooms

40,086 +



Food Allergy Appointments Completed in 2024

- Largest Global Food Allergy Treatment Center of Its Kind
- Unmatched Experience in Food Allergy Management

52%

Patients travel to Southern California for treatment

- 34 Countries
- 50 US States

30

Average # of months a patient is in TIP treatment



# Partnering with Food Allergy Institute

At Food Allergy Institute, we're committed to supporting physicians who want to provide their patients with more than just allergy management—we offer true remission. By partnering with us and utilizing our Tolerance Induction Program® (TIP), you can empower your patients with an innovative path to true food freedom. Together, we can help transform lives, offering children and families the hope and reality of living without food limitations or the constant fear of allergic reactions.

#### How does TIP work?



#### Safety-First Approach

- TIP employs biosimilar proteins to reduce risk and maintain reaction rates below 1%. TIP does not begin with primary allergen exposure.
- All patients have access to a 24/7 provider team for reaction support, facilitating seamless athome care.
- Each patient receives a personalized scenario plan, outlining specific medications for various exposure scenarios.
- TIP utilizes a proprietary gummy to safely deliver microdosed allergens, ensuring precise and controlled exposure throughout treatment.



#### **Treatment**

- TIP aims for true remission, allowing patients to eat freely without ongoing, daily maintenance.
- Over 90% of TIP treatment takes place at home with 4-6 in-person visits annually.
- TIP treats multiple food allergens simultaneously, instead of one allergen at a time.
- TIP uses AI-driven immune profiling to customize treatment for each patient based on biomarkers.



#### **Diagnostic Testing and Monitoring**

- All testing is performed by our own diagnostic laboratory to ensure the highest level of accuracy and consistency in testing, which is essential for developing highly individualized treatment plans.
- TIP relies on advanced diagnostics to track how the patient's immune system shifts, utilizing our proprietary machine learning platform Pantaleon™ to analyze patient data and optimize treatment progression.
  - o IgE & IgG4
  - Skin prick tests
  - Basophil activation tests

## Who Qualifies for Treatment with Food Allergy Institute?

TIP is for patients between the ages of 18 months - 25 years of age with IgE-mediated food allergies, regardless of severity or pre-existing conditions. Ideal candidates include children and young adults with multiple food allergies or a history of severe reactions, seeking a long-term solution beyond avoidance.

- 91% of patients have multiple anaphylactic food allergies
- 76% of patients have underlying health conditions
- 70% of patients never report a reaction during treatment
- 69% of patients currently see an allergist
- 30% of patients previously tried other forms of treatment

# Tolerance Induction Program® (TIP)

Each patient's food allergy treatment should be as unique as they are. The Tolerance Induction Program® (TIP) is built on over a decade of diagnostic data, leveraging trillions of data points, mathematics, and analytics to create a fully personalized, safe, and effective therapy tailored to each patient's immune system. As every new patient contributes to this growing data set, we continuously refine our understanding of food allergies, enhancing the efficiency and effectiveness of treatment.

At Food Allergy Institute, we are setting a new standard of care—moving beyond avoidance and desensitization to true tolerance. Through TIP, patients don't just manage allergies; they achieve remission, defined as seven days of sustained immune unresponsiveness with weekly protein exposure. With our data-driven, personalized approach, we are proud to be your partner in achieving lasting food allergy remission.

# How do we develop precision treatment plans with repeatable end points?



#### **Healthcare Meets Biotech**

We are a biotech company and healthcare provider with a dedicated research lab.



#### **Data Science**

We have collected over 15 years of data amounting to trillions of data sets.



## **AI-Driven Modeling**

We combine statistical methods like linear regression with machine learning to analyze patient data and forecast treatment outcomes.



## **Endotypes**

We utilize six technical endotypes of food allergy patients, taking into account T-cell and B-cell maturation as well as overall allergic profile



## **Phylogenetics**

We study plant protein biology and use biosimilar protein matching to determine the dosing strategy.

Once these relationships are identified, we can predict immune responses and design a treatment program to safely retrain the immune system.

# The TIP Journey: Phases and Milestones

#### Phase 1: Pre Treatment

Pre-treatment conditions the immune system for the safe introduction of anaphylactic foods by incorporating specific, non-allergenic foods into the diet 3-5 times per week. This phase is critical in preparing the immune system for successful tolerance induction.

#### **Key Components:**

- Immune System Mapping: A comprehensive blood panel (e.g., Basophil Activation Test BAT) and skin prick test to assess immune reactivity.
- Endotype Identification: Mapping the patient's unique immune system profile to understand their specific allergic responses.
- Environmental Allergy Assessment: Identifying environmental allergens that may impact food allergies (e.g., RAST testing) and determining if SLIT (Sublingual Immunotherapy) is necessary.
- Medical & Food Consumption History Analysis: A detailed review of the patient's medical history and dietary exposure to identify patterns influencing immune response and treatment planning.

#### **Key Milestones:**

 Personalized Treatment Plan Creation: Each patient receives a highly customized treatment roadmap, detailing the number of visits and quantity of food doses required to achieve remission. The platform analyzes trillions of data points, cross-referencing diagnostic results, patient history, and immune system mapping to ensure a precise, individualized treatment plan that evolves with new patient data.

## Phase 2: Conditioning

During this phase, biosimilar proteins are introduced to gradually shift foods from the sensitized column toward tolerance. These proteins mimic allergen structures, allowing the immune system to adjust safely and reduce reactivity before actual allergen exposure.

#### **Testing & Assessments:**

- Gastrointestinal Sensitivity Testing (Skin Patch Test)
- Lung Function Analysis (Pulmonary Function Testing)
- Plan Development: Ongoing review and refinement of the personalized treatment plan, continuously updated by the platform as new patient data is collected.
- Food Introductions & Challenges: Controlled introduction of foods in a structured challenge format to measure immune response and progress.
- At-Home Dosing: Regular, age- and weight-adjusted dosing at home.

#### **Key Milestones:**

- Successfully challenged biosimilar proteins.
- Cleared for commercial foods and cross-contaminated foods.
- Primary allergen IgE levels reduced by 50-70%.
- Introduction and successful challenge of primary allergens.

#### Phase 3: Tolerance Induction

Through data-driven analysis, the child will begin tolerance induction for anaphylactic proteins, with the first dose administered in the clinic and subsequent doses at home. Each successful dose predicts readiness for the next, leading to a full challenge pass. Once a food challenge is passed, a maintenance dose is given until blood work confirms tolerance, after which dosing frequency decreases.

#### **Key Milestones:**

- Maintenance Dosing: Gradually reducing the frequency of biosimilar maintenance foods.
- Routine Allergen Exposure: Continued exposure to maintain tolerance long-term.
- Final Steps Toward Food Freedom:
  - Take one day every week to try something new.
  - Stop reading food labels, safely consume cross-contaminated foods.
  - Enjoy unrestricted eating

#### Phase 4: Remission

Remission is achieved when all food allergens are fully tolerated, allowing patients to eat freely without restrictions or label-checking. Weekly maintenance dosing continues to support long-term tolerance and ensure sustained remission.

#### **Key Milestones:**

- Final Food Challenge: Achieving primary allergen tolerance (e.g., consuming 52 peanuts, stress testing, etc.), adjusted for age and weight.
- Maintenance Plan: Reducing dosing to once per week for continued immune regulation.
- Importance of Adherence: Consistent maintenance dosing helps lower IgE levels, clearing allergy-related antibodies from the immune system.
- Long-Term Outcome: With continued adherence, IgE levels are expected to decline to single digits—or even zero—within 2 to 4 years post-graduation.
- Achieve Full Food Freedom! Maintenance dosing is gradually reduced from weekly to biweekly and eventually to monthly, ensuring sustained remission.

## Why TIP is Different

At Food Allergy Institute, we deliver lasting remission and food freedom from allergy anxiety through a data-driven, personalized approach.

- Immune System Mapping: Advanced diagnostics pinpoint allergens, severity, and specific reactive proteins.
- Personalized Roadmap: Al-powered analysis determines the exact food doses and visits needed for remission.
- **Precision Gummy Dosing:** Our in-house lab creates allergen-specific gummies to safely train the immune system.
- **Real-time Adjustments**: Machine learning and frequent testing ensure ongoing treatment optimization.
- **Customized Scenario Plans**: Patients receive tailored exposure guides and emergency readiness plans.
- 24/7 Support: Our Command Center offers round-the-clock access to expert providers for immediate guidance.



# Provider Referral Program: How it Works

Partner with Food Allergy Institute to help patients access life-changing food allergy treatment while supporting education and awareness in your practice.

#### **Getting Started**

- 1. Complete the Referral Form (foodallergyinstitute.com/provider-partner-with-us)
  - This will generate your unique referral link.

#### 2. Check Your Inbox

• You'll receive an email confirmation with access to your personalized referral page.

#### 3. Receive Your Referral Toolkit

- Our team will provide the following resources:
  - Physician Referral Guide & TIP Overview
  - Anaphylaxis Training Posters (for lobby, exam rooms, and hallways)
  - Patient Handouts & Brochures (TIP overview + free EAI training info)
  - Food Freedom Cards (to encourage patient engagement)



#### When you Refer a Patient

- 1. Your Patient Submits Their Info.
  - Once a patient completes the form through your referral link, you'll receive a notification email.
  - The referral link ensures the patient and provider are associated throughout the process.

#### 2. Patient Begins Training

 The patient receives a link to complete the free Epinephrine Auto-Injector (EAI) training.

#### 3. Training Confirmation

- The patient receives a certificate upon training completion.
- You receive confirmation of their successful completion as well.

#### 4. Next Steps Toward TIP

• After training, the patient is invited to schedule a consultation for the Tolerance Induction Program™ (TIP), with our team managing all details from scheduling to insurance coordination.

#### 5. Patient Enrollment

 Once the patient enrolls in the program, you will receive a onboarding confirmation and regular patient updates.

# Referring a Patient to Food Allergy Institute

Thank you for helping families find long-term remission through the Tolerance Induction Program™ (TIP). Use the information below to confidently refer patients, share TIP, and stay connected.

#### Talking Points for Introducing TIP

A New Path for Food Allergy: From Avoidance to Remission

- Living with food allergies means constant vigilance food labels, restricted meals, birthday party stress.
- Traditional approaches like avoidance, OIT, or medications may offer partial protection but not full
- Food Allergy Institute's Tolerance Induction Program™ (TIP) is different it's designed to achieve remission, not just management.

#### Why TIP Is Different

- No lifelong daily maintenance dosing
- Treats multiple allergens at once
- Built for complex, high-risk cases
- Backed by 200+ trillion data points and thousands of patients
- Ends with safe, unrestricted eating

"I'm referring you to the Food Allergy Institute because TIP may be the most promising step forward in your food allergy journey. They offer a free consultation to share all program details and answer all of your questions."

#### **Discussing Cost**

- "Many families see it as an investment in a life without food allergy limitations."
- "The Food Allergy Institute team will go over all costs, payment plans, and coverage options before you commit."
- "TIP is a highly personalized program using advanced data and long-term support so it's not always fully covered by insurance."

"I'm recommending this because I believe it offers something no other treatment does: the possibility of true remission."

## Refer your Patients To a Life of Food Freedom

- 1. Briefly introduce FAI and TIP during the visit.
- 2. Submit the referral form via your referral link so we can track the patient and provide anaphylaxis training.
- 3. Our team will handle scheduling a consultation and next steps with the family.
- 4. Get updates on patient status (with consent).
- 5. Stay connected with our Practice Engagement Committee for ongoing education and patient updates.

